Case No.: 59010US002

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:

FLANNIGAN, PAUL J.

Application No.:

10/719959

Confirmation No.:

3577

Filed:

November 21, 2003

Group Art Unit

3772

Title:

RESPIRATORY FACEPIECE AND METHOD OF MAKING A FACEPIECE

USING SEPARATE MOLDS

# BRIEF ON APPEAL

Mail Stop: Appeal Brief-Patents

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

CERTIFICATE OF TRANSMISSION [37 CFR § 1.8(a)]

I hereby certify that this correspondence is being transmitted to United States Patent and Trademark Office on the date shown below via the Office electronic filing system.

January 9, 2008

Date

Signed by: Susan M. Dacko

Dear Sir:

This is an appeal from the Office Action mailed on August 22, 2007, finally rejecting claims 1-26.

#### Fees

- Any required fee under 37 CFR § 41.20(b)(2) will be made at the time of submission via EFS-Web. In the event fees are not or cannot be paid at the time of EFS-Web submission, please charge any fees under 37 CFR § 1.17 which may be required to Deposit Account No. 13-3723.
- Please charge any additional fees associated with the prosecution of this application to Deposit Account No. 13-3723. This authorization includes the fee for any necessary extension of time under 37 CFR § 1.136(a). To the extent any such extension should become necessary, it is hereby requested.
- Please credit any overpayment to the same deposit account.

A Notice of Appeal was submitted on November 9, 2007, and was received in the USPTO on November 9, 2007.

## **REAL PARTY IN INTEREST**

The real party in interest is 3M Company (formerly known as Minnesota Mining and Manufacturing Company) of St. Paul, Minnesota and its subsidiary 3M Innovative Properties Company of St. Paul, Minnesota.

## RELATED APPEALS AND INTERFERENCES

Appellants are unaware of any related appeals or interferences.

### STATUS OF CLAIMS

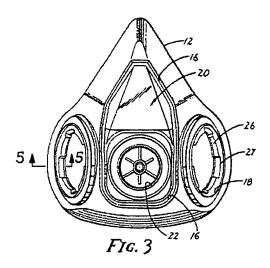
Claims 1-26 are pending and are the subject of this appeal. Each of these clams have been rejected under 35 USC § 102 or § 103.

### **STATUS OF AMENDMENTS**

No amendments have been filed after the final rejection.

# SUMMARY OF CLAIMED SUBJECT MATTER

Many respirators that are sold today use a thin rigid structural part for attaching filter elements and valves to the mask body. These rigid structural parts are commonly produced through injection molding and are often referred to as "rigid insert". A soft compliant material, which conforms to a person's face, is disposed on or about the rigid insert to enable the mask to fit snugly over the wearer's nose and mouth. The use of a rigid insert in conjunction with a soft compliant portion tends to make the mask lighter and more comfortable to wear, particularly when compared to previous masks that had used thick rubber throughout the whole mask body to support the filter cartridges and valves. Burns et al. (U.S. Patent 5,062,421) were the first persons to describe the rigid insert/compliant face-contacting member combination:

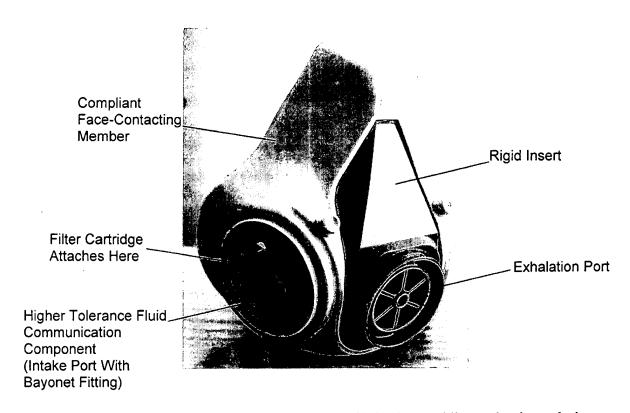


Burns et al.

Burns et al. surrounded the rigid insert 20 with an overmolded compliant facepiece 12 to reduce weight and product cost and to improve fit (see Burns et al., column 2, line 55 to column 3, line 2). Examples of subsequent masks that used a rigid insert in conjunction with a compliant face-contacting member are shown in U.S. Patent 6,298,849 to Scholey, U.S. Patent 6,016,804 to Gleason et al., and U.S. Patent 5,592,937 to Freund.

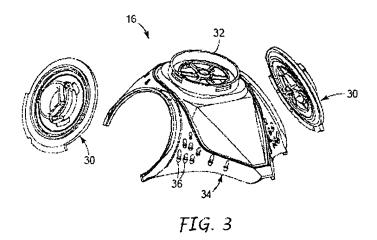
The rigid structural components that are employed in known mask facepieces have regularly incorporated multiple integrated elements that have distinct dimensional tolerance requirements and complex shapes. These high tolerance parts have been customarily formed in molds at relatively great expense.

Dimensional tolerance control — including actual dimension and conformation of an injected molded part — can be affected by the material used, the cycle time of the part, the mold configuration, and the part design. For a given material and a given part design, the factor that limits production typically is related to the element that has the greatest tolerance requirement. Higher tolerance parts, more-often-than-not, require additional oversight and technical expertise to correctly manufacture. For example, in the face piece shown below, the bayonet fitting has greater tolerance requirements than the supporting portion of the insert:



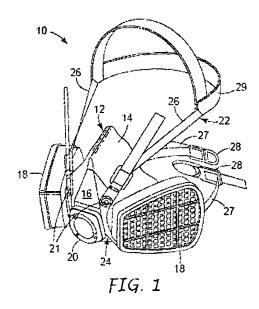
To properly utilize the efficiency and accuracy of injection-molding technology, designers have sought to encompass as much detail as possible in the mold so that the whole rigid insert can be manufactured in one step. The result therefore often involves complex tooling that is difficult to maintain and operate, especially when used in remote facilities that do not have access to well-trained technical resources. Thus, the higher tolerance requirements for certain portions of the rigid inserts — like the bayonet fitting shown above — can limit both the design and the production of the whole insert when made using conventional, single-stage, injection-molded technologies. Additionally, when a change to a feature in the facepiece insert is needed, such as a different filter mount, a whole new mold must be provided to make the change. That is, a separate mold must be furnished for the whole nosepiece and not simply for a portion of it.

The present invention provides a new method of making a facepiece insert 16 that has at least one fluid communication component 30, 32:



Applicant's method comprises: (a) providing a supporting portion 34 of a facepiece insert 16; (b) providing a fluid communication component 30, 32 separately from the supporting portion 34; and (c) securing the fluid communication component 30, 32 to the supporting portion 34 to form the facepiece insert 16 (page 2, lines 15-18; FIGs. 2 and 3).

The invention also provides a new method of making a respiratory mask body by securing a compliant face-contacting member 14 to the facepiece insert 16 so produced (page 2, lines 19-20):



The present invention further provides a new facepiece insert 16 that comprises:

(a) a supporting portion 34 of a facepiece insert 16; and

(b) a fluid communication component 30, 32 that is non-integrally joined to the supporting portion (page 2, lines 21-24).

In yet another aspect, the present invention provides a respiratory mask 10 that comprises:

- (A) a mask body 12 that includes:
  - (1) a facepiece insert 16 that includes:
    - (a) a supporting portion 34;
  - (b) at least one fluid communication component 30, 32 that is nonintegrally joined to the supporting portion 34 and that is a critical tolerance component; and
- (2) a compliant face-contacting member 14 that is non-integrally joined to the supporting portion 34 of the facepiece insert 16; and
- (B) a harness 22 for supporting the mask body 12 at least over a person's nose and mouth (page 4, line 27 to page 6, line 14, Figs. 1 and 2).

In the present invention, the fluid communication components 30, 32 — which commonly are critical tolerance components because they include more complicated and intricate filter attachment mounts 33 and valve seats — are provided in a first step, and, in another step, a supporting portion 34 of a facepiece insert 16 is joined to the fluid communication component 30. The facepiece insert 16 and its fluid communication components 30 may be made using, for example, injection molding procedures that are carried out as separate operations. The multistage operation may address the tolerance mismatch between the insert components 30, 32, and 34. Because the supporting part(s) 34 and the fluid communication part(s) 30, 32 of the insert 16 are separately provided, the inventive method can also support a beneficial distributed manufacturing scheme where fluid communication components 30, 32 can be produced in one location, with the associated expertise and equipment, and the final insert assembly 16 can be carried out in a second location, where the expertise and associated equipment are lacking. And if a change to the fluid communication component 30, 32 is needed, for example, to allow for a different type of filter attachment 18, the whole facepiece insert 16 does not need to be reconfigured in the mold. A separate mold need only be provided for the fluid communication component 30, 32 of the facepiece insert 16.

#### GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

## First Ground of Rejection

Claims 1-26 have been rejected under 35 USC § 132(a) for claiming subject matter that involves new matter. <sup>1</sup>

#### Second Ground of Rejection

Claims 1-4, 13, 14, 16-19, and 21-26 have been rejected under 35 USC § 102(b) for claiming subject matter that would have been anticipated by the disclosure in U.S. Patent 6,298,849 to Scholey.

## Third Ground of Rejection

Claims 5-12, 15, and 20 have been rejected under 35 USC § 103(a) for claiming subject matter that would have been obvious to a person of ordinary skill in view of Scholey's teachings

#### **ARGUMENT**

## First Ground of Rejection

Applicants' specification has been rejected under 35 USC § 132(a) for introducing new matter into the disclosure. In so doing, the Examiner has indicated that "[t]he added material which is not supported by the original disclosure is as follows: 'fluid communication component' not part of a filter cartridge."

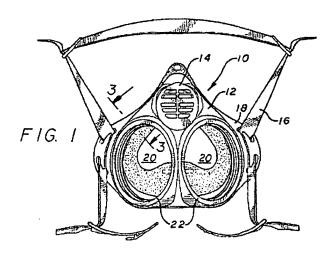
In applicants' Amendment mailed June 5, 2007, applicants amended the definition of "fluid communication component" to indicate that it is an element that is "not part of a filter cartridge". The applicants have directed the Examiner's attention to Figures 1 and 2 of applicant's specification and, in particular, to page 5, lines 16 to page 6, line 23. In these two paragraphs, the fluid communication components 30 and 32 are identified. These fluid communication components are shown as being parts that become parts of the face piece insert 16. The filter cartridge 18 is shown in Figure 1 as being a separate part that becomes attached to the face piece insert 16 at each of the fluid communication components 30 and 32 shown in Figure 2. In the paragraph that begins at line 25 of page 5, applicant specifically states that the

<sup>&</sup>lt;sup>1</sup> The Examiner has made an "objection" under this statutory provision. Applicants believe that the Examiner also intended to "reject" the claims. Accordingly, applicants request the Examiner's confirmation of such so that the Board has proper jurisdiction over this particular issue.

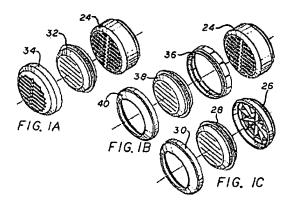
intake "fluid communication component 30 has a bayonet structure 33 that enables a filter cartridge 18...to be attached to the face piece insert 16." Thus, it is clear that the fluid communication component 30 is not part of a filter cartridge. Indeed, FIGs. 2 and 3 both show fluid communication components 30, 32 separate from the filter cartridge. Accordingly, the specification does support the language added to the definition. Applicants therefore respectfully request that the rejection under 35 USC § 132(a) be reversed.

## Second Ground of Rejection

Scholey describes a respiratory mask 10 includes a mask body 12, an exhalation valve 14, and a strap harness 16:

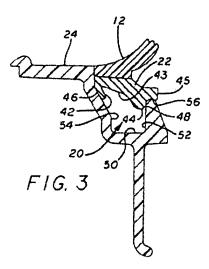


The mask body 12 is a unitary molded member of a thin rigid plastic and has overmolded portions 18 arranged around the inner face area of the mask to form a rubber-like flange member for supporting and sealing the mask to the face of the user (column 2, lines 43-47). Figures 1a-1c illustrate exploded views of filter cartridges or cartridge assemblies that can be used with the mask shown above:



Scholey states that "[t]he filter cartridges 24 are complete cartridges in themselves, whereas the filter assembly members 26 require additional members such as a replaceable filter member 28 and a cover member 30 to form a total filter assembly."<sup>2</sup>

An overmolded rubber-like flange member 22 is located within each cartridge opening 20 to receive and seal cartridges within the cartridge openings 20:



Two flange members 42 and 44 provide for two sealing surfaces 46 and 48 when used in combination with the filter cartridge 24 or a cartridge assembly member 26.

Applicants claim terms "compliant faced contacting member", "face piece insert", "fluid communication component", and "mask body" are reproduced below for ease of reference:

"compliant face contacting member" means the portion of a mask body that engages the facepiece insert directly or otherwise and is compliantly

<sup>&</sup>lt;sup>2</sup> See Scholey at column 2, lines 56-60.

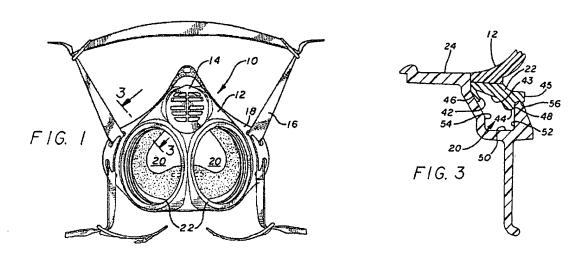
fashioned for making contact with a person's face to allow the mask body to be comfortably supported over a person's nose and mouth.

"facepiece insert" means a rigid element(s) that is fashioned to form part of the mask body but is made separate from the compliant face contacting member to provide structural integrity to the mask body to allow filtration elements and/or valves to be adequately secured thereto.

"fluid communication component" means an element that is not part of a filter cartridge and that is structured to allow a fluid to pass from an interior gas space to an exterior gas space or vice versa.

"mask body" means a structure that can fit over the nose and mouth of a person and that can help define an interior gas space separated from an exterior gas space.

In the Office Action, the Examiner identifies Scholey's filter cartridge 24 as being a "fluid communication component". As indicated above, applicants have amended the definition of "fluid communication component" to clearly specify that it is not part of a filter cartridge. The definition of fluid communication component in applicants' specification and claims clearly identify a filter cartridge as being a part separate from the fluid communication component. This is particularly true in view of claim 4 where a filter cartridge that is capable of being attached to the fluid communication component is recited. Because Scholey's parts 24 and 26 are clearly parts of the filter cartridge, applicants contend that they do not qualify as a fluid communication component as defined in the present application. In maintaining the rejection under 35 USC § 102, the Examiner states that "Figure 3 of Scholey shows that the fluid communication component being secured to the supporting portion of the face piece insert." Figure 3 is described by Scholey as being a cross-sectional view taken along lines 3-3 of Figure 1:



In FIG. 3 (unlike FIG. 1) "one of the cartridge or cartridge assemblies [FIGs. 1a-1c] is in position within the cartridge opening." Scholey indicates that the filter cartridge 24 is secured to the mask body 12 by having a rounded upper end 56 distort flange 44 upwardly so that the cartridge 24 can be snapped in position past the flange 44.

Figure 3 thus describes a snap securement of the filter cartridge 24 to the mask body 12. This figure does not illustrate the securement of a fluid communication component to the supporting portion of a face piece insert. The accompanying text also do not describe the step of providing at least one fluid communication component separately from the supporting portion of the face piece insert. Figure 3 only describes the securement of the filter cartridge to the rigid body portion 12 of the respiratory mask. As such, Scholey would not have anticipated applicants' invention under the terms of 35 USC § 102.

## Third Ground of Rejection

Claims 5-12, 15 and 20 also have been rejected under 35 USC § 103 for being obvious over Scholey. Applicants respectfully submit that this rejection too cannot be sustained. As indicated above, Scholey fails to suggest a fluid communication component that is secured to the supporting portion of a face piece insert. Without any teaching or suggestion of this basic feature of applicants' invention, Scholey would not have rendered applicants' invention obvious to a person of ordinary skill.

## **CONCLUSION**

For the foregoing reasons, appellants respectfully submit that the Examiner has erred in rejecting this application. Please reverse the Examiner on all counts.

Respectfully submitted,

January 9, 2008

Date

Karl G. Hanson, Reg. No.: 32,900

Telephone No.: 651-736-7776

Office of Intellectual Property Coursel 3M Innovative Properties Company

Facsimile No.: 651-736-3833

## CLAIMS APPENDIX

1. A method of making a facepiece insert that has at least one fluid communication component, which method comprises:

- (a) providing at least one supporting portion of a facepiece insert;
- (b) providing at least one fluid communication component separately from the supporting portion of the facepiece insert; and
- (c) securing the at least one fluid communication component to the at least one supporting portion.
- 2. A method of making a respiratory mask body, which method comprises the steps of claim 1 and further comprises:
  - (d) securing a compliant face-contacting member to the facepiece insert.
- 3. A method of making a respiratory mask, which method comprises the steps of claim 2 and further comprises:
  - (e) securing a harness to the mask body.
- 4. The method of claim 3, further comprising providing at least one filter cartridge that is capable of being attached to the at least one fluid communication component.
- 5. The method of claim 1, wherein the at least one fluid communication component is a critical tolerance component.
- 6. The method of claim 2, wherein the at least one fluid communication component is a critical tolerance component.
- 7. The method of claim 3, wherein the at least one fluid communication component is a critical tolerance component.
- 8. The method of claim 1, wherein the at least one supporting portion of the facepiece insert and the at least one fluid communication component are made from similar polymeric materials and are fused together.

9. The method of claim 1, wherein the at least one fluid communication component has a tolerance of less than 0.15 millimeters.

- 10. The method of claim 1, wherein the at least one fluid communication component has a tolerance of less than 0.1 millimeters.
- 11. The method of claim 1, wherein the at least one fluid communication component has a tolerance of less than 0.05 millimeters.
- 12. The method of claim 1, wherein the supporting portion of the facepiece insert has a tolerance of about 0.16 mm to 0.3 mm.
  - 13. A facepiece insert that comprises:
  - (a) a supporting portion; and
- (b) a fluid communication component that is non-integrally joined to the supporting portion.
- 14. A respiratory mask body that comprises the facepiece insert of claim 13, and further comprises a compliant face contacting member that is non-integrally joined to the supporting portion of the facepiece insert.
- 15. The respiratory mask body of claim 14, wherein the fluid communication component has a tolerance of 0.15 mm or less, and wherein the supporting portion has a tolerance of about 0.16 mm or greater.
- 16. A respiratory mask, that comprises the mask body of claim 14, and further includes a harness for supporting the mask body over a person's nose and mouth.
- 17. A respiratory mask, that comprises the mask body of claim 14, and further includes a filter cartridge for supporting the mask body over a person's nose and mouth.
- 18. The respiratory mask of claim 16, wherein the fluid communication component comprises part of an inhalation valve.

19. The respiratory mask of claim 16, wherein the fluid communication component comprises part of an exhalation valve.

- 20. A respiratory mask of claim 16, wherein the fluid communication component has a tolerance of 0.15 mm or less, and wherein the supporting portion has a tolerance of about 0.16 to 0.3 mm.
- 21. The respiratory mask of claim 16, wherein the supporting portion and the fluid communication component are fused together.
  - 22. A respiratory mask that comprises:
  - (A) a mask body that includes:
    - (1) a facepiece insert that includes:
      - (a) a supporting portion;
    - (b) at least one fluid communication component that is non-integrally joined to the supporting portion and that is a critical tolerance component; and
  - (2) a compliant face-contacting member that is non-integrally joined to the supporting portion of the facepiece insert; and
  - (B) a harness for supporting the mask body at least over a person's nose and mouth.
- 23. The respiratory mask of claim 23, further comprising at least one filter cartridge that is secured to the mask body at a location where the fluid communication component resides.
- 24. The method of claim 1, wherein the fluid communication component includes a means for allowing a filter cartridge to be attached thereto.
- 25. The The method of claim 13, wherein the fluid communication component includes a means for allowing a filter cartridge to be attached thereto.
- 26. The method of claim 22, wherein the fluid communication component includes a means for allowing a filter cartridge to be attached thereto.

# EVIDENCE APPENDIX

None.

# RELATED PROCEEDINGS APPENDIX

None.